May 18, 2011

Mr. Philippe Baechtold
Head, Patent Law Section
Sector of PCT and Patents,
Arbitration and Mediation Center, and
Global Intellectual Property Issues
World Intellectual Property Organization
34, chemin des Colombettes,
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Re: ITSSD Recommendations Regarding Agenda Items
Thus Far Addressed During 16th SCP Plenary Session

Dear Mr. Baechtold,

In light of the quick pace by which the Secretariat is tackling the items listed on the Revised Draft Agenda of the SCP's 16th plenary session, the Institute for Trade, Standards and Sustainable Development (ITSSD) seeks, for the sake of clarity, to convey in writing its impressions and to make the following recommendations:

1. Regarding Agenda Item #6:

The Revised Annex II of Document SCP/12/3 REV.2, as set forth in Document SCP/16/2, should contain within each of the seven (7) subsections of the document relating to the 'particular aspects of national patent law' designated, a specific reference to the primary ***and*** secondary legislation (e.g., a patent law of an IP code *and* Regulations under the primary legislation) relating thereto. The ITSSD, a nonprofit legal research and analytics organization, believes that if member state delegations provided specific references to their national legislative, statutory ***and*** regulatory sources of law, the Secretariat would facilitate the highest understanding by other member state, intergovernmental and nongovernmental delegations, and by the academic communities within all member states, of the multiple bases ***in law*** pursuant to which each member state acts with respect to the implementation and enforcement of its patent laws. This would, no doubt, also contribute to a much more informed, precise and constructive discussion of these subject matters by SCP members during future SCP meetings, which is likely the reason that more specific information has since been requested within Document SCP/16/3.

2. Regarding Agenda Item #7:

a. Each of the ten (I-X) sections of Document SCP/16/3 should seek substantiation of the applicable provisions in primary legislation/statutory law and in secondary administrative regulations given that they may be (there will likely be) divergences between the law as adopted and the law as implemented and enforced.

b. Each of the ten (I-X) sections of Document SCP/16/3 should contain references to the notion of 'adequate', 'full' and/or 'complete' *remuneration* contained within the provisions of the WTO TRIPS Agreement relating to 'exceptions and limitations to patent rights' by which each WIPO member state delegation is bound. In particular, the questionnaire should ask how, in terms of procedure and substantive analysis, each member state government arrives at the determination of what constitutes 'adequate' remuneration.

c. Section VII of said document should contain a question relating to the treatment of product and process information and data formally labeled by IP holders as a 'trade secret' or otherwise as 'proprietary and/or confidential' information and/or data to ensure the adequate protection thereof from unauthorized and/or inadvertent disclosure to third parties within and beyond government. The questionnaire should ask about the rules and procedures each member state government has in place for identifying and protecting such designated process and product information and data, including the penalties it would impose for violation of such rules and procedures by government employees. In the United States, for example, such unauthorized disclosures could lead to the imposition of civil as well as criminal penalties.

d. Furthermore, during the discussion of this Agenda Item on Monday, May 16, the delegate from El Salvador made an interesting point concerning the distinction between judicial rulings interpreting primary and secondary laws and regulations relating to exceptions and limitations of the patent right, on the one hand, and judicial decisions that reflect judicially created doctrines that go beyond primary and secondary law, on the other hand, and whether such rulings should be accorded equal treatment for purposes of the questionnaire and the SCP's analyses of these issues. There is also the related point that the ITSSD recommends be discussed in the questionnaire regarding the uncertain state of the laws in this area within many member states. The ITSSD recommends that two additional subparts be added to those questions within each of the ten sections of the document seeking information about 'case law': a) To what extent, if any, is your country's case law undecided or in a state of 'uncertainty' concerning the availability and/or treatment of such use(s)? b) Please indicate if there is a 'split' among the courts of your country on this issue, by region or district with respect to the availability and/or treatment of such use(s), and cite all cases relating thereto.

e. Section VI of said document does not contain any reference to national law that implements international treaty provisions (e.g., of the United Nations Convention on the Law of the Sea – UNCLOS) prescribing the treatment of IP rights developed from activities of member state nationals undertaken in the marine/global ocean commons – areas beyond national jurisdiction (ABNJ) on floating vessels and/or on floating or anchored platforms. The ITSSD recommends that the Secretariat, at a minimum, consult the following resources to learn more about this subject matter and how it would affect member state patent laws relating to the treatment of joint research and experimental projects involving both nationals and foreign third parties undertaken in the marine/ocean global commons. See, e.g.:

"It is evident...that the sources of revenues that can be derived from the oceans are much more varied and extensive: they can be from the deep ocean bed, from fishing on the high seas, from

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taxes on trade through freight and over-flight and on passenger traffic, from a system of taxes, user charges, fines and permits for commercial activities in the Southern Ocean and others. These resources can be placed in a general fund for general international use. A significant part, however, should be allocated specifically for ocean governance and development. Activities for these purposes are also myriad: there is a need for regulation, enforcement of the provisions of the Law of the Sea...for research on ocean resources and the way it influences climate and might in the twenty-first century even be used to forecast or modify climate and regional weather patterns." See Ruben P. Mendez, *Ocean Governance and Development: The Question of Financing: The Global Commons: Disputed and Encroached Areas, in Ocean Governance: Sustainable Development of the Seas*, (Peter Bautista Payoyo Ed.) The United Nations University ©1994, at: http://www.unu.edu/unupress/unupbooks/uu15oe/uu15oe0u.htm .

"[T]he Convention [UNCLOS] provides fairly clear grounds for denying patentability for products derived from pure marine scientific research and for those covering organisms themselves collected in the Area... "Countries with biotechnology industries have asserted either that Part XI accommodates "bioprospecting" (biological or genetic research carried out for commercial purposes) under the high seas freedom of marine scientific research, or that UNCLOS is simply not relevant to bioprospecting. The result of either view would be international patenting of deep sea living resources on a first-come-firstserved basis. This has provoked concern by developing countries, who have expressed concern that the fruits of marine scientific research cannot be owned at all, or else ought to be viewed as 'common heritage of mankind' subject to ISA regulatory and revenue-sharing jurisdiction. This [author] largely avoids this debate by focusing on the question precedent: whether the need for a new deep sea intellectual property regime is felt by a sufficient plurality of nations to make a new property rules agreement a viable political and legal necessity. In answering this antecedent question in the affirmative, this [author] briefly analyzes this intersection of TRIPS and UNCLOS and finds that the Convention provides fairly clear grounds for denying patentability for products derived from pure marine scientific research and for those covering organisms themselves collected in the Area"" See Peter Prows, *Tough Love: The Dramatic Birth and Looming Demise of UNCLOS Property Law* (July 10, 2006). NYU Law School, Public Law Research Paper No. 06-19 at pp. 55-56, Abstract at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=918458 ; http://www.tilj.org/journal/42/prows/Prows%2042%20Tex%20Intl%20LJ%20241.pdf *Cf.* Chika B. Onwuekwe, *The Commons Concept and Intellectual Property Rights Regime: Whither Plant Genetic Resources and Traditional Knowledge?*, 2 Pierce Law Review 65-90 (March 2004) at: http://nessiteras.piercelaw.edu/assets/pdf/pierce-law-review-vol02-no1-onwuekwe.pdf (distinguishes between the concept of the "commons" and closely related terms often confused with it such as 'open access', 'common property,' 'shared resources', and 'communal resources' or 'communal property'. This article argues that PGRs [plant genetic resources] are not within the category of commons recognized under international law or any other known jurisprudence. It further contends that equating the "air" or "outer space" with "plant plasm" is a misnomer because such an approach undermines the concept of sovereign control of natural resources (renewable and non-renewable) within a country's territory") Id., at p. 69. *See also* Christopher Garrison, *Beneath the Surface: the Common Heritage of Mankind*, Knowledge Essentials Studies, Vol. 1 (2007) at: http://kestudies.org/ojs/index.php/kes/article/viewDownloadInterstitial/21/38 ("...considering what

might happen if it were decided that the biomedical invention landscape... were to be treated as an [A]rea in accordance with the principle of the Common Heritage of Mankind... a landscape covered with a grid, where each grid square contains a discrete invention. To discover each new invention involves "exploring' the landscape in much the same way as [A]reas of the seabed are explored... Firstly, it will not permissible for any private or public entity to 'own' outright any of these biomedical inventions... Secondly, biomedical inventions would have to be managed for the benefit of all humanity... Thirdly, the benefits from these biomedical inventions must be shared amongst all humanity... Fourthly, biomedical inventions must only be used for peaceful purposes. Fifthly, scientific research must be able to be freely carried out and the results of this research, freely published in accordance with the scientific method, for the benefit of all humanity") (emphasis added). Id., at pp. 76-77, and 79.

"[S]ome countries [namely, during early 2006, the G77 and China, had sought to define the legal status of marine genetic resources as falling under the 'common heritage of mankind' principle rather than the 'freedom of the high seas' principle]...stressed that the benefits arising from marine genetic resources should be shared with developing countries by expanding the jurisdiction of the International Seabed Authority (ISA) or through new international regulations. While they pointed to article 136 of the UN Convention on the Law of the Sea as justification for the relevance of the common heritage of mankind to marine genetic resources, the US and Japan argued that this regime applies only to mineral resources whereas marine genetic resources should be subject to the freedom of the high seas principle, namely that the high seas are open to all States, and pointed to article 87 of UNCLOS to justify their position." See *Legal Status of Marine Genetic Resources in Question*, Bridges Trade BioRes Vol. 6, No. 4 (March 3, 2006) at: http://ictsd.org/i/news/biores/62912/ . See also *An Update on Marine Genetic Resources: Scientific Research, Commercial Uses and a Database on Marine Bioprospecting*, United Nations Informal Consultative Process on Oceans and the Law of the Sea Eight Meeting, (United Nations University (June 2007) available online at: http://www.ias.unu.edu/resource_centre/Marine%20Genetic%20Resources%20UNU-IAS%20Report.pdf .

"The United Nations Convention on the Law of the Sea (UNCLOS) prohibits privatization or territorial control over the deep seas. The Convention on Biological Diversity (CBD) recognizes sovereign rights over biodiversity within national territories, but the World Trade Organization (WFO) permits privatization of microorganisms and plans to incorporate seeds and plants. Yet both the high seas and biodiversity (gene pool) could be viewed as the common heritage of mankind- necessary for human life, to be shared by all." *See* Carol B. Thompson, *International Law of the Sea/Seed: Public Domain versus Private Commodity*, 44 Natural Resources Journal 841 (2004) accessible online at: http://lawlibrary.unm.edu/nrj/44/3/08_thompson_sea.pdf .

At least one recent study "reveals a lack of information regarding the specific terms of common public-private partnerships for bioprospecting, including information on the practical applications of deep seabed genetic resources. Addtionally, the current patent classification system does not allow easy identification of patents based on the use of deep seabed genetic resources.

Scientifically, the paper notes a shift from conventional to genomics and bioinformatics-driven approaches. The current international legal framework, which comprises the United Nations Convention on the Law of the Sea (UNCLOS), the Convention on Biological Diversity (CBD), intellectual property rights instruments, and regional marine related instruments, does not adequately address the conservation of, access to, and benefit-sharing related to, deep seabed resources." See S. Arico and C. Salpin, *Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects*, Abstract (Institute of Advanced Studies. United Nations University, (UNU-IAS) (2010) available online at: http://cloud2.gdnet.org/cms.php?id=research_paper_abstract&research_paper_id=9356 ; Previous version of said document (2005) available online at: http://www.ias.unu.edu/binaries2/DeepSeabed.pdf .

"Marine bioprospecting in areas within national jurisdiction has been the subject of comparatively little direct interest among the scholars and in State discourse. The topic comes up mostly in wider discussions about the status of genetic resources under national jurisdiction, and in relation to ABS mechanisms. Commentators, however, have voiced concerns about alleged loopholes in the regulation of marine bioprospecting, especially in areas beyond national jurisdiction. Although the current legal regime may not be as inconsistent as some suggest, it is true that the responsibility for conservation and sustainable use of marine genetic resources in areas beyond national jurisdictions currently lies with individual States, with few tools available for actual international supervision. Since, in practice only public and private institutions from a limited number of wealthier States possess the technology for deep-sea bioprospecting, the current regime effectively entrusts much of marine genetic resources to a few States. That reality raises serious questions regarding conservation and sustainable use, but also regarding how benefits deriving from the commercial use of such resources can be shared in the interest of mankind." See Nicolas Leroux and Makane Moïse Mbengue, *Deep Sea Marine Prospecting Under UNCLOS and the CBD*, The University of New South Wales (Sydney, Australia 2010), at: http://www.gmat.unsw.edu.au/ablos/ABLOS10Folder/S3P1-P.pdf .

The ITSSD appreciates the Secretariat's serious consideration of the recommendations set forth above and any further recommendations the ITSSD is likely to submit during the remainder of the SCP's 16th plenary session.

Very truly yours,

Lawrence A. Kogan

Lawrence A. Kogan
President